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March 15, 1999

Food and Drug Administration Office of Special Nutritionals (HFS-450) Center for Food Safety and Applied Nutrition 200 C Street, SW Washington, DC 20204 319

Dear Sirs:

Notice is hereby given pursuant to the requirements of Section 403(r)(6) (21 U.S.C. § 343(r)(6)) of the Federal Food, Drug, and Cosmetic Act and in accordance with the requirements of 21 CFR § 101.93, that Rexall Sundown, Inc. located at 6111 Broken Sound Parkway, N.W., Boca Raton, Florida 33487 has marketed a dietary supplement within the last thirty days under the Sundown Herbals brand name bearing the following statement(s) on the label and/or in the labeling:

<u>Saw Palmetto Complex</u>: For prostate and urinary health. Saw Palmetto berries contain a variety of compounds including free fatty acids and sterols that help support prostate and urinary health. In Sundown Saw Palmetto Complex, Saw Palmetto is combined with carefully selected additional natural ingredients, which are helpful for promoting proper prostate and urinary health.

The undersigned certifies that the information contained in this notice is complete and accurate and that Rexall Sundown, Inc. has substantiation that the statement is truthful and not misleading. Pursuant to § 101.93 (a)(1), two copies of this notification are enclosed.

Sincerely,

Deborah Shur Trinker

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Vice President of Regulatory Affairs and Assistant General Counsel

Enclosure